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APPARATUS FOR PROVIDING AN INDICATION OF A SENSATION

Technical Field

The present invention relates generally to an apparatus for assessing the level of comfort or discomfort in a positive or negative sensation experienced by a person, and more particularly to an electronic apparatus being devised to provide a variable stimulus to the person until the applied stimulus matches the experienced sensation.

Background

In medical as well as psychological treatment there is a need to quantify the sensation experienced by the patient, for example in order to select an appropriate treatment and to determine the need of drugs or the effect of a pursued treatment. This is based in the individual need for an adequate treatment as well as for conveying an understanding of the personal situation for example to a doctor. There is also a social need to control the overall consumption of drugs and the general well-being of the population. In order to meet these and other needs, an efficient tool for quantifying sensations, particularly those related to medical or psychological disorders, is required.

The best known field for quantifying sensations is perhaps the assessment of pain, and prior art within this field has evolved from general statements of the status in response to questions from a doctor to simple aids such as the widely used sliding scale for quantifying a sensation of pain. A disadvantage with these methods is the unreliability inter alia due to a relative scale which is strongly dependent on unconscious or conscious subjective influence by the patient.

In order to produce a more reliable result an electronic instrument and a method for measuring an arbitrary feeling e.g. pain or nausea has been suggested and presented in the patent publication WO 97/24068 (Laserow), which is herewith incorporated by reference. This instrument is devised to apply a physical stimulus to the patient, e.g. in the form of an electrical current, and the stimulus is increased until the patient experiences a discomfort that is comparable to the pain or nausea that is to be quantified. The patient then actively or passively ceases the induced stimulus and a value is registered. It has been found that this way of quantifying pain or other discomfort is repeatable and more reliable than previous methods. Furthermore, the measurement is unbiased since the patient is not aware of the resulting value only of the stimulus to be compared to the feeling to be assessed.

Another prior art method directed to the quantification of the emotional state following a dysphoric condition, such as depression, anxiety or pain, is disclosed in US Patent No. 4,844,091 to Bellak. This piece of prior art describes a method wherein an increasing acoustical stimulation is applied to a patient until the level of the acoustic al stimulation is associated with the level of the dysphoric condition.

It is well known that many sensations have a sensory component as well as an

affective component. This fact entails difficulties in determining the appropriate measures to be taken against for example a dysphoric condition. So may, for example, a much lesser amount of analgesics actually be needed in order to eliminate pain than the measurement value according to prior art method suggests. In other situations, e.g. where a mainly emotional sensation should be assessed there is in prior art an uncertainty as to what component is actually measured.

Accordingly, there is a need for an improved apparatus that gives a reliable and repeatable indication of the different components of the experienced sensation.

Objects of the Invention

It is therefore an object of the present invention to solve the problem of providing an improved apparatus that is easy to handle and gives an efficient indication of a selected component of a sensation.

An aspect of the problem to be solved is to distinguish between the sensory and the affective components of sensations. More particularly, this aspect of the problem concerns how to measure the sensory and the affective components, respectively.

Another aspect of the problem is to provide a suitable type of stimulation.

Yet another aspect of the problem to be solved is to achieve a way of checking the reliability of a measurement.

Summary of the Invention

The present invention is based on the realisation of the inventors that the result of the measurement is dependent on the type of the applied stimulus. The basic principle of the invention is to let a person compare an induced stimulus with a current or a previously experienced sensation by making an analogy between the sensation caused by the induced stimulus and the sensation to be measured. It has been found by the inventors that sensations to be measured are best compared with a pulsating stimulus in order to achieve a reliable result. In parts of a measurement or for measuring specific sensations or components of sensations, a constant stimulus, which can be regarded as a pulsating stimulus having an infinite pulse width, may be used. Stimuli according to different embodiments of this invention are for example electrical current and heat.

Furthermore, the sensory component of a sensation has been found to be best compared with a pulsating stimulus where the amplitude is varied, in most cases increased, in order to determine a level of this component. The sensory component typically reflects the intensity or strength of a compound sensation having both components. Likewise, it has been found that the affective component of a sensation is best compared with a pulsating stimulus where the pulse width is varied, in most cases increased, in order to determine the relevant level. The affective component typically reflects the level of comfort or discomfort in a compound sensation having both components. When measuring a sensation

known to have none or only a negligible amount of one of the components, it is of course sufficient to apply the stimulus suitable for the mainly occurring component.

Different sensations may, according to an embodiment of the invention, also be measured by applying different frequencies for different sensations. There are physiological as well as a psychological reasons for this, i.e. physical stimuli having certain frequency settings are suitable for comparing certain sensations. When conducting measurements on different types of sensations it is also psychologically appropriate to vary the type of stimulation in order to separate the sensations in the mind of the measured person.

According to an embodiment of the invention, the reliability of a measurement is checked by conducting a series of measurements with different variations in the stimulation. In embodiments of the invention this variation is achieved by varying the increase rate of the pulse width or the pulse amplitude. Thus, if an increasing stimulation is maintained for the same period in two different stimulation sequences of the same measurement session, different results will be obtained. Thereby it is possible to detect erroneous measurement conditions or an unconscious or conscious attempt to manipulate the measurement.

The reliability of the measurement is in another embodiment of the invention checked by first detecting and storing the perception threshold of the person, by gradually increasing the stimulation until the person signals a perceived stimulation. In a similar manner the sensation threshold of the person is detected, i.e. the threshold at which the patient begins to experience a similar or an analogue sensation. This threshold is perhaps mostly used in connection with pain measurement where it is consequently called pain threshold, i.e. the patient begins to experience pain. Again in a similar manner, the tolerance threshold of the person is detected and stored when the person signals an unbearable stimulation. It has been found by the inventors that the most relevant measurement results are obtained in the range between the perception threshold and the tolerance threshold. In a subsequent measurement session the scales of the measurement values are then adjusted dependent on the stored individual threshold values. For checking purposes, it is utilised by the invention the fact that it is unlikely that someone would estimate a sensation as corresponding to a stimulus below the perception threshold. In ordinary measuring, valuable measuring time is saved by starting the stimulation close to the perception threshold. Furthermore, it is preferable to adjust the scale running from absence of sensation to unbearable sensation such that it starts on the perception threshold.

Brief Description of the Drawings

The invention will now be further described in conjunction with the drawings, wherein Fig 1 shows a block diagram of the functional components of the inventive apparatus.

Detailed Description of Embodiments

The invention facilitates the measurement of sensations, perceptions and integrated skills and disabilities. In compound sensations both the sensory as well as the affective component can be measured. Examples of sensations, perceptions and integrated skills and disabilities include pain, nausea, tinnitus, tiredness, muscle weakness, spasticity, vomiting need, anxiety, fear, state of being, abstinence, itch, luxation, heartbeat, cramp, suffocation, allergy, sleep, sensitivity, motoric problems, ache, apathy, ataxia, aphasia, athetosis, degree of infection, fever, numbness, swelling, intoxication, inflammation, burning, cognitive or mnemonic ability, joy, comfort, vision, paresthesia, dysphagia, sweating reflexes, movement, quality of life, ADL (active daily living skills), etc.

The invention is mainly intended to be applied in a portable measurement device such as the one disclosed in the above mentioned prior art document WO 97/24068 (Laserow). Fig 1 shows a block diagram of the functional structure of the invention, thus comprising a stimulus signal generator 102 coupled via means 106 for providing a pulsating stimulus to stimulus induction means 104, which in use are intended to be applied to the skin of a person for inducing a stimulus. A control unit 114, for example a control processor, is coupled to the stimulus signal generator 102 via an amplitude variation means 120 devised for varying the amplitude of the pulsating stimulus signal and thereby the output stimulus in order to measure the level of a sensory component of a sensation. The control unit is also coupled to the pulsating stimulus providing means 106 via a pulse width variation means 122 devised for varying the pulse width of the pulsating stimulus signal in order to measure the level of an affective component of a sensation. The control unit is further coupled to a memory 116 for storing registered measurement values and control instructions for predetermined control schemes, and a display 118 for the visual presentation of an obtained measurement value or other information. The control unit is also optionally coupled to a control switch 124, e.g. a button, for starting, stopping or halting a measurement sequence at for example a perception threshold, sensation threshold, tolerance threshold or sensation level. In a preferred embodiment, the apparatus is devised to stop a variation of the pulsating properties of the stimulus in response to an actuation of the control switch 124, and the apparatus is devised to keep the pulsating property at its current level. So, for example, may the patient stop an increase in amplitude or pulse width at a level which seems to match the measured sensation and consider whether the level is correct. If the patient indeed considers the level to be correct, the patient releases his or her contact with the induction means 104. This leaves an open circuit which is detected by the apparatus, whereupon it is devised to automatically store the current value of amplitude and/or pulse width. If the halted level is not considered to be corrected, the patient may continue the increase, or variation, by releasing the button or switch back to an initial switch position.

In the embodiment as shown in Fig 1, the means 106 for providing a pulsating stimulus further comprises means 108 for providing a pulsed current stimulus intensity, e.g. in the shape of an oscillator, and/or means 110 for providing a square waved stimulus intensity, e.g. in the shape of a square wave or a triangle wave generator, either of the means 108 and 110 being devised to provide a stimulus signal in the form of a pulsed current having a frequency in the range of 1-100 Hz. In Fig 1 is also shown a switching means, controllable by the control unit and being devised to switch between the different wave forms.

In Fig 2, a more specific embodiment devised for delivering stimuli in the shape of a pulsated electrical current is shown. One of two electrodes 204 is coupled to a switched power supply 216 which in its turn is coupled or couplable to an energy source 218, e.g. a battery. The second electrode 204 is coupled to a constant current generator (CCG) 202 for generating a stimulus signal. The switched power supply 216 and the constant current generator 202 are coupled to a microprocessor 206 provided with an in/out (I/O) interface 212 such as a key board and/or a display. The pulses are generated by means of the microprocessor and conveyed to the electrode 204 from the constant current generator 202 via a digital to analog converter (D/A) 210 coupled intermediate the microprocessor 206 and the constant current generator 202. In this embodiment the amplitude variation means, the pulse width variation means and means for achieving a selected pulse shape are realised by a specific program run on the microprocessor. Different curve forms and increase rates are in a similar manner also achieved by the microprocessor.

An analog to digital (A/D) converter 208 is further coupled between the constant current generator 202 and the microprocessor 206 in order to facilitate a feedback for detection of closed or open circuit between the electrodes. This detection is provided in order to control the start of a measurement sequence when the electrodes are gripped by a person and/or the registration of a measurement value when the electrodes are released by said person and the circuit is broken.

In a first embodiment devised for applying an electrical current stimulus, the stimulus signal generator comprises a constant current generator capable of delivering an electrical current through a resistance preferably in the range of 0-20 kohm. The electrodes of preferred embodiments of the apparatus are intended to be applied to the skin of the persons to be measured. The electrodes are thereby preferably devised to contact the skin between the fingers in a tweezers grip and are therefore provided with a metal surface or a conductive silicone rubber surface.

This apparatus would further be capable to vary the amplitude of an electrical current stimulus signal in the range of 0-100 mA, preferably increasing with incremental steps in the range of 0.5 mA and preferably having a fixed pulse width in the range of 50-1000 microseconds. The apparatus would also or instead further be capable to vary the pulse width of an electrical cal stimulus signal in the range of 0-1000 microsecond,

preferably increasing with incremental steps in the range of 5-10 microseconds and preferably having a fixed amplitude in the range of 5-20 mA.

In order to increase the reliability of the measurement apparatus as discussed above, one embodiment is devised to increase the pulse width of the electrical current stimulus signal at a first increase rate in a first pulse width range, preferably such that the pulse width increases from 0-250 microseconds in 15-40 seconds, and at a second increase rate in a second pulse width range preferably such that the pulse width increases from 251-500 microseconds in 20 seconds. The apparatus is further devised to increase the amplitude of an electrical current stimulus signal at an increase rate in an amplitude range, for example such that the amplitude increases from 0-100 mA within a certain time period, which time period may be last between 5 and 80 seconds.

The purpose of using different time periods for the increase of pulse width or amplitude within a specific range, and thus the increase rate, is to make the measurement independent of the subjected person's perception of time. With varying increase rates from one test to another, the person subjected to the test is not led to make his or her indication based on the memory of the previous test, regarding the time elapsed since the beginning of the stimulus induction. The person therefore needs to focus only on the induced stimulus, which in turn results in a more reliable measurement. For this reason, the inventive apparatus is devised to never use the same time period, for a certain increase range and a certain person, twice in a row. Preferably the apparatus is devised to change said time period randomly, although at least 5 seconds, between every two tests.

In order to adjust the scales of the measurement result, one embodiment of the invention is devised to increase the stimulation signal starting at a signal level dependent on a previously stored perception threshold. This perception threshold is preferably found in a dedicated measurement cycle. Likewise is another embodiment devised to increase the stimulation signal up to a signal level dependent on a previously stored sensation or tolerance threshold.

In addition to the operation with increasing current and/or heat amplitude, as well as increasing pulse width, the inventive apparatus is capable of running according to a randomized stimulation scheme. In such a scheme, the induced stimuli has a random value both with regard to amplitude and, for electrical current, pulse width. Preferably, higher values close to the tolerance threshold are avoided in the randomized stimulation scheme. A certain random value, or set of values, is maintained for a specific time period, long enough for a person to be able to indicate that the stimuli matches the sensation to be measured. After said time period, the induced stimuli assumes a new random value, or set of values.

In one variety of the inventive apparatus the stimulus induction means 104 comprises a heat generating devise for emitting a stimulus in the form of heat. Different examples of such heat generating devices are resistive coils, peltier elements and lasers,

such as argon lasers or carbon dioxide lasers. When using heat as stimulus, the apparatus would be devised to provide a heat stimulus having an amplitude increasing in a range of 20-60 centigrades, preferably increasing with incremental steps in the range of 0.1 centigrades. The increase rate would typically be varied such that the heat stimulus increases from a start temperature to a maximum temperature during an interval in the range of 10-60 seconds.

According to one embodiment of the present invention, the apparatus comprises the described means for induction of stimuli in the form of both an electrical current and heat.

The choice of using heat as stimuli, instead of an electrical current, can be dependent on the sensation to be measured. Test results have shown that pain thresholds were elevated following intrathehal morphine when using an argon laser technique for heat stimuli induction, whereas no pain threshold changes were detected using electrical stimulation. A hypothetical explanation to the different results has been that the morphine has different effects on different nerve fibre populations, of which C-fibres are activated by heat and A-delta fibres are activated by electrical stimulation. Similar results have been found when measuring pain threshold elevation following treatment with acupuncture.

According to the invention, the apparatus can be used not only to indicate sensations, but also integrated skills, impairments and disabilities, e.g. quality of life and active daily living, ADL. When using the apparatus for such a purpose, the measured perception threshold and pain threshold are used as lower and upper values on a scale, or vice versa. The integrated skill is then indicated by selecting the appropriate stimulation level, and the measurement result is referred to said scale. The induced stimuli can be either an electrical current or heat. Furthermore, the measurement, or indication, can be performed either by the person subjected by the stimuli, or by another person, based upon this other person's realisation of the integrated skills of the subjective person.

In an exemplifying prototype used for an experimental study of an aspect of the invention, an electrical current stimulus was provided by means of an electrical current generator capable of delivering a current through a resistance of 13 kohm. The current was pulsated in a pulsating square wave shape having a fixed amplitude of 10 mA and a frequency of 10 Hz. The pulse width was increased from 0 to 500 microseconds in steps of about 8 microseconds. The increase rate of the pulse width was devised such that the pulse width was increased from 0 to 250 microseconds during 25, 30 or 35 second, never repeating the same increase rate twice in a sequence, and from 251 to 500 microseconds during 20 seconds. The results of this experimental study verifies the proper function of the invention.

A preferred procedure for using the inventive apparatus for measuring a sensation, using a stimulus signal with an increasing value, comprises the steps of:

- connecting the induction means 104 to a skin portion of the patient, preferably into a finger grip;

- commencing the stimulus induction by pushing the control switch 124, whereupon an increasing stimulus is generated;
- the patient halting the increase of the stimulus signal when sensing that the induced stimulus matches the sensation to be measured, whereby the stimulus signal is held at a constant level;
- the patient considering if said constant level matches the sensation to be measured;
- if indeed considering the stimulation halted at the constant level to represent a good match, the patient releasing the grip of the induction means, the resulting open circuit ending with the released induction means thereby triggering the apparatus to store the currently generated stimulus level;

if not considering the stimulus at the constant level to match with the sensation to be measured, the patient pushing the control switch once again, thereby continuing the increase from the halted level, until finding a better level.

As previously described, the inventive apparatus can also be used for measuring a perception or an integrated skill, and may furthermore use a random variation of the stimulus signal instead of an increasing value. The described procedure is however easily modified to any of those cases, and is not intended to be limited by the specific wording of the included steps.

Claims

1. An apparatus for measuring the level of a sensation, perception or integrated skill of a person, the apparatus being provided with:
-a stimulus signal generator (102) coupled to stimulus induction means (104) for inducing a physical stimulus to said person;
-means (124), actuateable by said person, for indicating that a stimulus is experienced by the person to correspond to the level of said sensation;
-level registration means (114,116) for registering a sensation level value corresponding to said sensation,
characterized in
means (106) for providing a pulsating stimulus and means (120,122) for varying the pulsating properties of the stimulus in order to measure the level of a selected sensation or a selected component of said sensation.
2. The apparatus of claim 1, further comprising means (120) for varying the amplitude of said pulsating stimulus in order to measure the level of a sensory component of said sensation.
3. The apparatus of claim 1, further comprising means (122) for varying the pulse width of said pulsating stimulus in order to measure the level of an affective component of said sensation.
4. The apparatus of claim 1, wherein the stimulus signal generating means (102) further comprises a direct current generator capable of delivering a current through a resistance of 0-20 kohm via stimulus induction means (104) in the shape of electrodes applicable against the skin of said person.
5. The apparatus of claim 1, wherein the pulsating stimulus providing means (106) further comprises an oscillator (108) being devised to provide a stimulus signal in the form of a sinus wave having a frequency in the range of 1-100 Hz.
6. The apparatus of claim 1, wherein the pulsating stimulus providing means (106) further comprises a square and/or triangular wave generator (110) being devised to provide a stimulus signal in the form of a square wave having a frequency in the range of 1-100 Hz.
7. The apparatus of claim 5 or 6, further being capable of varying the amplitude of an electrical current stimulus signal in the range of 0-100 mA, preferably increasing with incremental steps in the range of 0.5 mA and preferably having a fixed pulse width in the range of 50-1000 microseconds.
8. The apparatus of claim 5 or 6, further being capable of varying the pulse width of an electrical cal stimulus signal in the range of 0-1000 microsecond, preferably increasing with incremental steps in the range of 5-10 microseconds and preferably having a fixed amplitude in the range of 5-20 mA.

9. The apparatus of claim 5 or 6, further being devised to increase the pulse width of an electrical current stimulus signal at a first increase rate in a first pulse width range, preferably such that the pulse width increases from 0-250 microseconds within a time period between 15 and 40 seconds, and at a second increase rate in a second pulse width range preferably such that the pulse width increases from 251-500 microseconds in 20 seconds.
10. The apparatus of claim 5 or 6, further being devised to increase the amplitude of an electrical current stimulus signal at an increase rate in an amplitude range, preferably such that the amplitude increases from 0-100 mA within a time period between 5 and 80 seconds.
11. The apparatus of claim 9 or 10, further being devised to change said time period between every two tests, when using the same increase range for one and the same person.
12. The apparatus of claim 5 or 6, further being capable of generating an electrical current stimulus signal with random amplitude and pulse width values, within predetermined levels, for a certain time period, after said time period being devised to generate a new stimulus signal with random amplitude and pulse width values.
13. The apparatus of claim 1, further being devised to increase the stimulation signal starting at a signal level dependent on a previously stored perception threshold.
14. The apparatus of claim 1, further being devised to increase the stimulation signal up to a signal level dependent on a previously stored sensation or tolerance threshold.
15. The apparatus according to any of the previous claims, wherein the stimulus induction means (104) comprises a heat generating devise for emitting a stimulus in the form of heat.
16. The apparatus of claim 15, wherein the heat generating device is a resistive coil or a peltier element.
17. The apparatus of claim 15, wherein the heat generating device is a laser, such as an argon laser or carbon dioxide laser.
18. The apparatus of claim 15, further being devised to provide a heat stimulus having an amplitude increasing in a range of 20-60 centigrades, preferably increasing with incremental steps in the range of 0.1 centigrades.
19. The apparatus of claim 15, further being devised to vary the increase rate such that the heat stimulus increases from a start temperature to a maximum temperature during an interval in the range of 10-60 seconds.
20. The apparatus of claim 15, further being capable of generating a heat stimulus with a random amplitude value, within predetermined levels, for a certain time period, after said time period being devised to generate a new heat stimulus with a random amplitude value.
21. The apparatus of claim 4, wherein the electrodes have a metal surface to be applied to

the skin of the person.

22. The apparatus of claim 4, wherein the electrodes have an electrically conductive silicon rubber surface to be applied to the skin of the person.

23. The apparatus of claim 1, further comprising a control switch (124) devised to stop a variation of the pulsating properties of the stimulus, the apparatus thereby being devised to keep the pulsating property at its current level.

24. The apparatus of claim 1, comprising means (208) for detecting a closed or open circuit between a pair of said stimulus induction means (104), the apparatus being devised to automatically store a currently generated stimulus signal value when detecting an open circuit.

Abstract

An apparatus for measuring the level of a sensation, perception or integrated skill of a person, the apparatus being provided with stimulating means for inducing a physical stimulus to the person and means for registering a sensation level value in response to an indication signal from the person that the induced stimulus corresponds to the sensation to be measured. The apparatus is devised to provide a pulsating stimulus having means for varying the pulsating properties of the stimulus, such as providing a variable amplitude in order to measure the level of a sensory component of the sensation and a variable pulse duration in order to measure the affective level of the sensation.
(Fig. 1)

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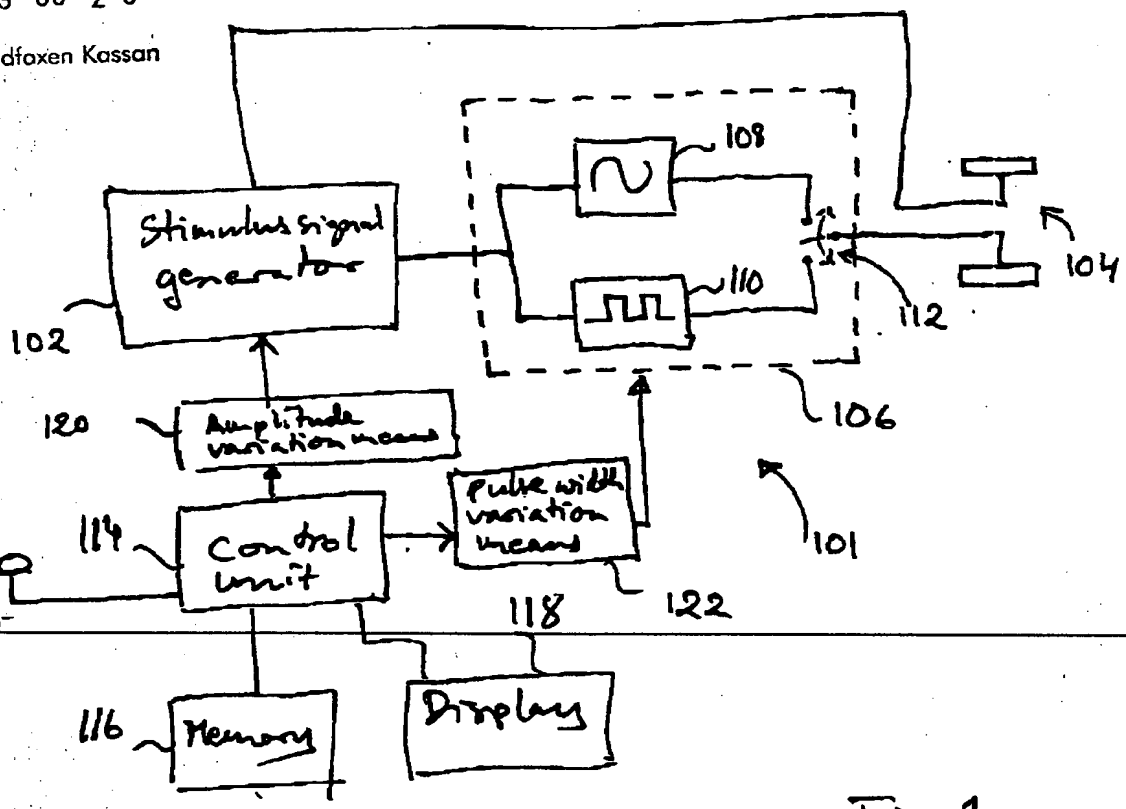

Fig 1.

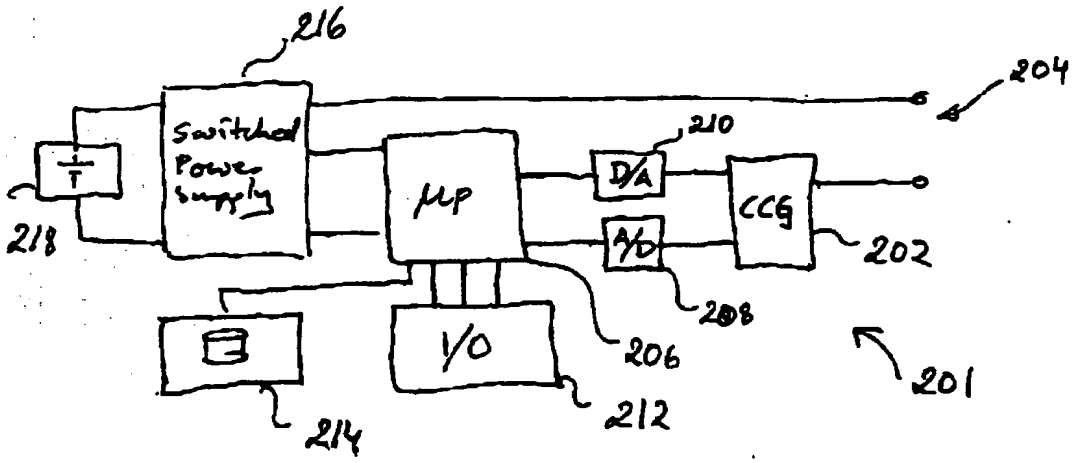

Fig 2